



Use of Certificates of Confidentiality (CoC) in Research

Established:	May 19, 2016
Responsible Office	Office of the Vice President for Research
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Summary

A Certificate of Confidentiality (CoC) adds a layer of privacy protection for participants enrolled in sensitive research. A CoC primarily protects against compulsory legal demands, such as court orders and subpoenas that would identify an individual as a research participant. Though most frequently granted by the National Institutes of Health (NIH), they may also be granted by the Food and Drug Administration (FDA; for trials with an Investigational New Drug (IND) and/or Investigational Device Exemption (IDE)), and are available even to non-funded studies. CoCs are appropriate for research studies that gather information about subjects that might be damaging, and which will only exist in the research study records (that is, the information isn't already in other records that are subject to subpoena).

POLICY STATEMENT:

The purpose of this policy is to:

- a) Describe the types of studies eligible for a CoC
- b) Describe the types of studies that should NOT operate under a CoC
- c) Describe the documentation required for a CoC
- d) Describe the procedures required to uphold a CoC

RESPONSIBILITIES:

The Principal Investigator (PI) is responsible for obtaining a CoC for applicable investigator-initiated studies. For sponsor-initiated studies, the PI is responsible for obtaining appropriate institutional authorization for the CoC and maintaining appropriate written assurances. The PI is also responsible for ensuring that the research informed consent language accurately reflects any limits of the CoC. Finally, the institution is responsible for upholding the CoC and providing legal counsel for any legally required reporting that would be protected under the CoC.

POLICY:

1. **Studies occurring at MUSC that would be eligible for a CoC include those research studies that are collecting sensitive information that does not originate from the medical record. CoCs are not appropriate for studies where all research data are derived from the medical record (e.g. chart review).**
2. **Research studies collecting sensitive information may include but are not limited to the following:**
 - a. Research on HIV, Acquired Immune Deficiency Syndrome (AIDS), and other sexually transmitted diseases (STD)
 - b. Studies that collect information on sexual attitudes, preferences, or practices
 - c. Studies on the use of alcohol, drugs, or other addictive products
 - d. Studies that collect information on illegal conduct
 - e. Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community
 - f. Research involving information that might lead to social stigmatization or discrimination if it were disclosed
 - g. Research on participants' psychological well-being or mental health
 - h. Genetic studies, including those that collect and store biological samples for future use

3. Information in the legal medical record may be subject to subpoena or other appropriate access use or disclosure; Investigators conducting studies that require study participation to be documented in the legal medical record where clinical billing to insurance will occur should not obtain a CoC.
4. For sensitive studies that require documentation in the medical record ONLY for scheduling, ordering or billing clinical services (not to insurance) a CoC may still be obtained, however de-identification at the participant level will be performed by the Health Information Management Team (see Policy: Research Documentation in the Legal Medical Record).
5. Based on the NIH CoC FAQ (referenced below), a CoC will be considered valid at MUSC only if the MUSC PI has signed an assurance that the PI will uphold the CoC.
6. Since the Institution is responsible for upholding the CoC and providing appropriate legal counsel if warranted, CoCs should also be signed/authorized by an Authorized Official (Director, Assistant Director, or designee) within the Office of Research and Sponsored Programs (ORSP) at MUSC.
7. For studies with a CoC, the consent language regarding the protections afforded by the CoC must be approved by the Institutional Review Board (IRB).
8. For multisite studies in which the sponsor has obtained a CoC, the appropriateness of the local application of the CoC must be reviewed. Specifically, issues to be determined include:
 - a. Is the study collecting sensitive information that would not otherwise be found in the medical record?
 - b. Is it the intention of the sponsor that MUSC will be covered under the CoC, or is the CoC only for a part of the study (e.g. the CoC covers only the biorepository aspect)?
 - c. Does the study require identifiable information regarding study participation to be entered into the participant's medical record for the purposes of documentation of clinical care or clinical billing?
9. In the event that item 8c. above is YES, language regarding the additional protections of the CoC should NOT be included in the Informed Consent Document, since the Institution cannot guarantee that information found in the medical record would not be subpoenaed or otherwise appropriately used or disclosed. In this case, the Institution could still argue that the identifiable information in the medical record that would be covered under the CoC should be protected, but the participant would not be given any false assurances.

PROCEDURE:

MUSC Investigator Initiated CoCs:

1. Prior to submitting an application for a CoC, the PI must obtain institutional approval. The PI will submit the CoC application and a completed copy of the MUSC CoC Checklist for review and signature to the Institutional Official (ORSP).
2. An Authorized Official will determine the appropriateness of the need for a CoC based on the information in the MUSC CoC Checklist.
3. The PI will maintain a copy of the CoC application as well as the CoC for review and/or audit.
4. If the PI changes, the new PI must also sign a CoC assurance for the Institution to remain covered under that CoC and must also notify the agency that issued the CoC.

Sponsor (non-MUSC) Initiated CoCs:

1. For studies in which the sponsor has obtained a CoC, it must be determined whether the sponsor is expecting MUSC to also adhere to the CoC:
 - a. If the CoC is applicable only for the Sponsor (and not MUSC), it is acceptable to include language regarding the sponsor's CoC in the informed consent document. If study participants will be documented as such in the legal medical record, there should also be appropriate language in the

informed consent document that states that any information in the legal medical record may still be subject to subpoena.

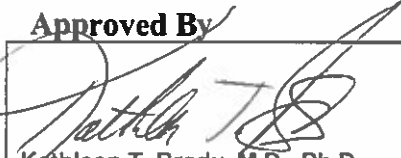
- b. The MUSC PI will submit a signed copy of his/her CoC assurance letter, the sponsor's CoC, and the MUSC CoC Checklist to the MUSC Authorized Officials within the Office of Research and Sponsored Programs at MUSC (Director, Assistant Director, or designee) for review and approval.
2. The Authorized Official will determine whether it is appropriate for MUSC to fall under the CoC based on the criteria above.
3. Any questions or concerns regarding the appropriateness of the CoC should be directed to SCTR's Regulatory Knowledge and Support Core.
4. After the CoC is approved by the MUSC Authorized Official, the PI must send a copy of his/her signed assurance letter to the sponsor or sponsor's designee.
5. The IRB will have final approval as to what is included in the Informed Consent Document.

Contact Information

For information regarding the overall policy and related documents, please contact the SCTR SUCCESS Center, (843-792-8300, success@musc.edu). For questions related to specific department roles/responsibilities, please contact the applicable department directly.

Related Information

NIH Certificates of Confidentiality (CoC) Kiosk <http://grants.nih.gov/grants/policy/coc/index.htm>
NIH Certificates of Confidentiality (CoC) FAQs <http://grants.nih.gov/grants/policy/coc/faqs.htm#366>
MUSC Policy: Research Documentation in the Electronic Medical Record
MUSC IRB Informed Consent Template
Notice of Privacy Practices

Approved By	Information Contact	Effective On:
 Kathleen T. Brady, M.D., Ph.D. Vice President for Research	South Carolina Clinical & Translational Research Center (SCTR) SUCCESS Center	May 19, 2016